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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,847	10/26/2001	Charles E. Hart	00-100	9351

7590 12/24/2002
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

EXAMINER

CHEN, LIPING

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,847

Applicant(s)

HART ET AL.

Examiner

Liping Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 in part, 2-8 and 12, drawn to a method of improving kidney function in a mammal in need comprising administering to the mammal a composition comprising a therapeutically effective amount of a zveg4 protein in combination with a pharmaceutically acceptable delivery vehicle, wherein the zveg4 protein is a disulfide-bonded dimer of two polypeptide chains, each of said chains consisting of residues x-y of SEQ ID NO:2, classified in 514, subclass 12.
- II. Claims 1 in part, 2-7 and 9-12, drawn to a method of improving kidney function in a mammal in need comprising administering to the mammal a composition comprising a therapeutically effective amount of zveg4 protein-encoding polynucleotide in combination with a pharmaceutically acceptable delivery vehicle, wherein the zveg4 protein is a disulfide-bonded dimer of two polypeptide chains, each of said chains consisting of residues x-y of SEQ ID NO:2, classified in 424, subclass 93.2.
- III. Claims 13 in part and 14-20, drawn to a method of enhancing proliferation or survival of kidney tubule epithelial cells in a mammal comprising administering to the mammal a composition comprising a therapeutically effective amount of a zveg4 protein in combination

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with a pharmaceutically acceptable delivery vehicle, wherein the zveg4 protein is a disulfide-bonded dimer of two polypeptide chains, each of said chains consisting of residues x-y of SEQ ID NO:2, classified in 514, subclass 12.

- IV. Claims 13 in part, 14-19 and 21-23, drawn to a method of enhancing proliferation or survival of kidney tubule epithelial cells in a mammal comprising administering to the mammal a composition comprising a therapeutically effective amount of zveg4 protein-encoding polynucleotide in combination with a pharmaceutically acceptable delivery vehicle, wherein the zveg4 protein is a disulfide-bonded dimer of two polypeptide chains, each of said chains consisting of residues x-y of SEQ ID NO:2, classified in 424, subclass 93.2.

In addition, upon the election of any of groups I-IV, further election of a patentably distinct species of x and y value is required.

The inventions are distinct, each from the other because:

Groups I and III and groups II and IV are distinct from each other because they are drawn to using compositions having different chemical structures, physical properties and biological functions: protein or polynucleotides, respectively, for therapeutic purpose in a mammal, which require separate search. Search for protein does not require search for polynucleotide, and vice versa. Since the

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classification for groups I and III are different with groups II and IV, they are not obvious variants and deemed patentably distinct.

Group I and group III are distinct from each other because they are drawn to distinct methods: improving kidney function or enhancing proliferation or survival of kidney tubule epithelial cells, which comprise different population. These methods differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables, and criteria for success. Thus, groups I and II are patentably distinct from each other.

Group II and group IV are distinct from each other because they are drawn to distinct methods: improving kidney function or enhancing proliferation or survival of kidney tubule epithelial cells, which comprise different population. These methods differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables, and criteria for success. Thus, groups I and II are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Pauline Farrier, Patent Analyst, at (703) 305-3550. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice

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published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Liping Chen, Ph.D.
Patent Examiner
Group 1632

PETER PARAS
PATENT EXAMINER

Pete Paras